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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,727	ORFAO, ALBERT	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 7, recites the limitation "sorting the large-capturing particles..." It is unclear as to what is encompassed by "sorting". For example, are the large-capturing particles sorted from each other, or are they sorted from the unbound materials in the sample?

Claim 1 is also confusing because the preamble of the claim is not consistent with the body of the claim. The preamble recites a process for isolating molecules but the last step fo the claim is directed to sorting particles.

Claim 8, line 1, recites the limitation "the distinction". There is insufficient antecedent basis for this limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-10 and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Burger et al., 4,904,581.

Burger discloses a process for isolating molecules, cells and other particles which are specifically bound to a large particle comprising : incubating a sample with at least one set of large-capturing particles (see column 10, lines 17-27, and lines 37-44, and column 14, lines 25- line 32) each of which are able to specifically bind/capture a large number of molecules, cells or other particles contained in the sample (see column 10, lines 25-36, and column 14, lines 31-47); analyzing the large-capturing particles containing specifically bound molecules, cells or other particles (see column 11, lines 1-5, and column 14, lines 21-23); sorting the large-capturing particles containing specifically bound molecules, cells or other particles (see column 11, lines 1-5.) Sorting is defined by Examiner to mean separating the large-capturing particles containing specifically bound molecules, cells or other particles from the unbound material in the sample. (This is also the description of sorting given by Applicant in the specification.)

As to claim 2, said large-capturing particles may be of different sizes, materials, densities, and/or shapes, (see column 10, lines 19-25.)

As to claim 3, different types of molecules, cells or other particles can be bound to the large-capturing particles (see column 10, lines 19-25, and line 59 – column 11, line 5.)

As to claim 4, the large-capturing particles are covered with or bound to specific antibodies, parts of antibodies, oligonucleotides or other types of probes specific for the binding of the molecules, cells and other particles of interest (see column 10, line 59 – column 11, line 5.)

As to claim 5, the sample is simultaneously or sequentially incubated with two or more different sets of large-capturing particles for the isolation/depletion of two or more different types of molecules, cells or other particles from the sample (see column 5, lines 34-53, and column 16, lines 25-46.)

As to claim 6, each set of large-capturing particles can specifically bind one, two or more different types of molecules, cells or other particles from the sample (see column 10, lines 59-68.)

As to claim 7, the incubation of the sample with the large-capturing particles is performed by: (A) directly mixing the large-capturing particles with the sample (see column 8, lines 44-47); (B) passing the sample through a chamber containing the large-capturing particles (see column 9, line 62 – column 10, line 7, and column 10, line 59 – column 11, line 23); or (C) passing the large-capturing particles through the sample (see column 9, line 62 – column 10, line 7, and column 10, line 59 – column 11, line 23.)

As to claim 8, the distinction between the large-capturing particles bound to the molecules, cells or other sample particles is based on their scatter, fluorescence or both (see column 11, lines, 23-25.)

As to claims 9 and 15, the large-capturing particles bound to molecules, cells or other sample particles are sorted into Petri dishes or microtiter plates (see column 10, lines 29-31.

As to claim 10, different sample volumes and amounts of large-capturing particles can be used in combination, (see column 10, lines 59-63.)

As to claim 12, the molecules are DNA, mRNA, proteins, or peptides (see column 14, lines 41-43.)

As to claim 13, the other particles are chromosomes, mitochondria, zymogen granules or cell membranes (see column 4, lines 32-34.)

As to claim 14, the large particle is latex or polystyrene (see column 10, lines 37-44.)

3. Claims 1-8 and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Sutton et al., 5,308,749.

Sutton discloses a process for isolating molecules, cells and other particles which are specifically bound to a large particle (column 16, lines 33-36) comprising : incubating a sample with at least one set of large-capturing particles (see column 16, lines 36-38) each of which are able to specifically bind/capture a large number of molecules, cells or other particles contained in the sample (see column 8, lines 10-15; see also column 1, lines 52-54); analyzing the large-capturing particles containing specifically bound molecules, cells or other particles (see column 14, 7-9); sorting the

large-capturing particles containing specifically bound molecules, cells or other particles (see column 16, lines 34-44 and column 17, lines 14-16.) Sorting is defined by Examiner to mean separating the large-capturing particles containing specifically bound molecules, cells or other particles from the unbound material in the sample. (This is also the description of sorting given by Applicant in the specification.)

As to claim 2, said large-capturing particles may be of different sizes, materials, densities, and/or shapes, (see column 8, lines 5-6.)

As to claim 3, different types of molecules, cells or other particles can be bound to the large-capturing particles (see column 8, lines 10-15, and column 16, lines 32-36.)

As to claim 4, the large-capturing particles are covered with or bound to specific antibodies, parts of antibodies, oligonucleotides or other types of probes specific for the binding of the molecules, cells and other particles of interest (see column 11, lines 3-21.)

As to claim 5, the sample is simultaneously or sequentially incubated with two or more different sets of large-capturing particles for the isolation/depletion of two or more different types of molecules, cells or other particles from the sample (see column 16, lines 32-40.)

As to claim 6, each set of large-capturing particles can specifically bind one, two or more different types of molecules, cells or other particles from the sample (see column 16, lines 35-36.)

As to claim 7, the incubation of the sample with the large-capturing particles is performed by passing the sample through a chamber containing the large-capturing particles (see column 16, lines 36-38.)

As to claim 8, the distinction between the large-capturing particles bound to the molecules, cells or other sample particles is based on their scatter, fluorescence or both (see column 14, lines 7-9; and column 15, lines 7-9.)

As to claim 10, different sample volumes and amounts of large-capturing particles can be used in combination, (see column 16, lines 32-40.)

As to claims 12 and 13, the molecules are DNA, mRNA, proteins, or peptides (see column column 16, lines 40-42.) As to claim 13, Examiner notes that "other molecules" in claim 1, line 5, is listed as an alternative.

As to claim 14, the large particle is latex or polystyrene (see column 5, line 1.)

As to claim 15, the large-capturing particles bound to molecules, cells or othe sample particles are sorted into receptacles (column 17, lines 8-11.)

4. Claims 1-8 and 10-13, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Wood, 5,290,707.

Wood discloses a process for isolating molecules, cells and other particles which are specifically bound to a large particle (column 5, lines 15-21) comprising : incubating a sample with at least one set of large-capturing particles (see column 3, lines 46-53) each of which are able to specifically bind/capture a large number of molecules, cells or

other particles contained in the sample (see column 5, lines 15-21); analyzing the large-capturing particles containing specifically bound molecules, cells or other particles (see column 6, lines 35-40); sorting the large-capturing particles containing specifically bound molecules, cells or other particles (see column 5, lines50-56.) (Sorting is interpreted here by Examiner to mean separating the large-capturing particles containing specifically bound molecules, cells or other particles, (i.e., reference 60 in Wood), from agglutinating bodies (24), (see column 5, lines 41-47.)

As to claim 2, said large-capturing particles may be of different sizes, materials, densities, and/or shapes, (see column 4, lines 61-65.)

As to claim 3, different types of molecules, cells or other particles can be bound to the large-capturing particles (see column 5, lines 19-21.) (Antigen and antibody are considered to be different types of molecules or particles.)

As to claim 4, the large-capturing particles are covered with or bound to specific antibodies, parts of antibodies, oligonucleotides or other types of probes specific for the binding of the molecules, cells and other particles of interest (see column 5, lines 19-21.)

As to claim 5, the sample is simultaneously or sequentially incubated with two or more different sets of large-capturing particles for the isolation/depletion of two or more different types of molecules, cells or other particles from the sample (see column 4, lines 61-65.)

As to claim 6, each set of large-capturing particles can specifically bind one, two or more different types of molecules, cells or other particles from the sample (see column 5, lines 19-21.)

As to claim 7, the incubation of the sample with the large-capturing particles is performed by directly mixing the large-capturing particles with a sample containing molecules, cells or other particles of interest (column 4, lines 46-53.)

As to claim 8, the distinction between the large-capturing particles bound to the molecules, cells or other sample particles is based on their scatter, fluorescence or both (see column 4, lines 29-31.)

As to claim 10, different sample volumes and amounts of large-capturing particles can be used in combination, (column 4, lines 46-47.)

As to claims 12 and 13, the molecules are DNA, mRNA, proteins, or peptides (see column 5, line 22.) As to claim 13, Examiner notes that "other molecules" in claim 1, line 5, is listed as an alternative.

As to claim 15, the large-capturing particles bound to molecules, cells or other sample particles are sorted into receptacles (column 5, lines 57-60.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton et al., 5,308,749, in view of McCafferty et al., 5,969,108.

Sutton discloses the invention substantially as claimed (see above), except for the large-capturing particles bound to molecules, cells or other sample particles being sorted into Petri dishes or microtiter plates.

McCafferty discloses a method including use of affinity chromatography to separate components and sorting them into Petri dishes (column 45, lines 3-12.) It would have been obvious to one of ordinary skill in the art to sort the large-capturing particles bound to molecules, cells or other sample particles in the Sutton method into Petri dishes, as taught by McCafferty, as a known type of receptacle for holding assay materials.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wood, 5,290,707, in view of McCafferty et al., 5,969,108.

Wood discloses the invention substantially as claimed (see above), except for the large-capturing particles bound to molecules, cells or other sample particles being sorted into Petri dishes or microtiter plates.

McCafferty discloses a method including use of affinity chromatography to separate components and sorting them into Petri dishes (column 45, lines 3-12.) It would have been obvious to one of ordinary skill in the art to sort the large-capturing particles bound to molecules, cells or other sample particles in the Wod method into Petri dishes, as taught by McCafferty, as a known type of receptacle for holding assay materials.

Response to Arguments

Applicant's arguments filed February 3, 2004 have been fully considered but they are not persuasive, except with respect to claim 11, the rejection of which is withdrawn with respect to the Burger reference.

Applicant argues on page 7 that the Burger references relates to method of detecting the binding and not to sort out the cells with bound antibody. However, Examiner asserts that Applicant has not claimed what Applicant means by sorting (see claim 1, line 7, for example.) Therefore, the step of separating bound particles from unbound particles and fluid in the sample is considered the step of "sorting". Also, with respect to the preamble, Applicant has not specified from what is the molecules, cells and other particles which are specifically bound to a large particle isolated. Therefore, the step of separating bound particles from unbound particles and fluid in the sample is considered the step of "isolating" as described in the preamble.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marchand et al., 5,217,905, discloses a bead (20) with several antibodies attached (see Figure 3.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

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